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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,576	06/13/2001	Clifton A. Alferness	59013-331623	7153

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

MAIL DATE	DELIVERY MODE
12/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/880,576	ALFERNESS ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,32-35,37 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,32-35,37 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 June 2001 and 27 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 10, 2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 18, 32-35, 37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lederman et al (6,224,540 B1) in view of Gordon et al (5,336,253).

Lederman et al disclose a passive girdle for constraining heart expansion and further disclose accessing the heart (the heart has to be accessed in order to place jacket 30 on the heart); selecting a device (30) sized to be placed on the diseased heart; placing the device (30) on the heart, the device (30) comprising compliant biocompatible material (33) configured to engage a surface of the heart to passively constrain circumferential expansion of the heart (See Column 5, lines 35-36); securing the device (30) on the heart (See Column 5, lines 52-55); the device (30) is secured to

the heart using sutures (See Column 5, lines 52-55, attaching the device at 4-6 points along the A-V groove suggests the use of sutures because an adhesive would be incompatible on a beating heart); adjusting the device (30) to snugly conform to the external geometry of the heart (See Column 5, lines 55-57); the biocompatible material (33) is a substantially non-elastic material (See Column 5, lines 26-31, the plastic rings allow expansion of the heart to a specified size and then constrains the heart); and the device (30) is configured to engage a surface of the heart to constrain circumferential expansion of the heart beyond a predetermined maximum volume (See Column 5, lines 26-31, see explanation above).

Lederman et al however fail to disclose passing an electrical element into the heart; passing an electrical current to the heart using the electrical element, the current selected to apply and electrical therapy to the heart; the electrical elements are pacer leads; the electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy.

Gordon et al disclose a pacing and defibrillation lead for providing therapy to a heart and further disclose passing an electrical element into the heart (see Column 2, lines 55-60; Column 3, lines 17-18; Column 4, lines 30-33; the lead is run through the superior vena cava and into the right ventricle, in order to place the electrode at the apex of the heart); passing an electrical current to the heart using the electrical element, the current selected to apply an electrical therapy to the heart (see Column 2, lines 55-60; and Column 3, lines 61-68); the electrical elements (10) are pacer leads; the

electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy. See also: Column 2, lines 40-48; and Column 6, lines 34-54.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lederman et al to include the application of electrical therapy to the heart, as per the teachings of Gordon et al, since it is well known in the art to utilize pacing and/or defibrillation to treat an abnormally-beating heart, which would provide a secondary means of therapy to the heart.

Response to Arguments

4. Applicant's arguments filed October 10, 2007 have been fully considered but they are not persuasive.

The Applicants have amended Claim 18 to add the step of "passing an electrical element through an open area in the device" in an attempt to overcome the current rejection of Lederman et al and Gordon et al. Current Claim 18 discloses placing a heart jacket on the heart for therapy. In order to place a jacket onto the heart, the jacket needs an open area, so the jacket can be placed on the heart so that one end of the jacket is adjacent to the A-V groove when secured onto the heart. During the placement of electrical leads, as disclosed in Gordon et al, the leads are placed within the heart at the ventricular apex. In order to place the leads at the ventricular apex of the heart, the leads would have to be run through the superior vena cava and then into the heart, and thus, through the open area in the jacket in order to reach the ventricular apex of the

heart. Based on the current claim language, the combination of Lederman et al and Gordon et al still teach the current claims.

The Applicants argue that neither Lederman et al nor Gordon et al provide any teaching or suggestion for the current combination. To provide the device of Lederman et al with a further means of treating the heart, it would have been obvious to one of ordinary skill in the art, in view of the teachings of Gordon et al, since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e., one skilled in the art would have recognized that the open cell construction of the heart jacket in Lederman et al would allow the placement of electrical leads in the heart tissue, as taught by Gordon et al, for providing a secondary means of treating a diseased heart. See *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

The Applicants further argue Lederman et al teaches away from using a heart jacket in combination with an electrical stimulation therapy. The Applicants cite a prior art means, in Column 2, lines 17-21 in Lederman et al, for treating a heart by placing a skeletal muscle around the heart and using a pacemaker to stimulate the skeletal muscle to help the heart contract, whereas the invention of Lederman et al teaches a passive device for treating the heart. The disclosure in Lederman et al of a passive device does not teach away from providing an electrical stimulation therapy to the heart. The pacemaker cited in Column 2, lines 17-21 is not used for stimulating the heart, but

instead for stimulating the skeletal muscle wrapped around the heart. The stimulation of the implanted skeletal muscle creates an active restraint means, whereas the disclosure of Lederman et al is for a passive device. Therefore, the disclosure of Lederman et al teaches away from using an active restraint means, but does not teach away from using an electrical stimulation therapy for the heart.

Based on the current claim language, the prior art of Lederman et al and Gordon et al, as combined above, still teach all of the claimed limitations. Therefore the prior art rejection of Lederman et al and Gordon et al is being maintained.

Conclusion

5. This is an RCE of applicant's earlier Application No. 09/880576. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Szmal
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